REMARKS

The Advisory Action dated November 5, 2009 is acknowledged. Claims 1 and 3-40 are pending in the instant application and claims 1, 3-15, 25-37 and 39-40 remain rejected. Claims 16-24 and 38 are withdrawn. By the present response, claims 1, 9 and 10 have been amended and claim 13, 14 and 25 have been canceled. In particular, claims 1, 9 and 10 have been amended for purposes of clarification. As set forth in the Advisory Action, the objection to claims 2 (currently canceled) and 39 is withdrawn. However, the rejections of the claims are maintained. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1, 3-15 and 25-37 under 35 U.S.C. 103(a)

Claims 1, 3, 5, 14, 25 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2007/0190117 (Asmussen, et al.) in combination with U.S. Patent No. 6,599,511 (Asmussen, et al.). The Examiner argues that '117 teaches a film-shaped medicament for buccal administration of galanthanmine and at least one further pharmaceutically active substance, which is preferably selected from the group comprising acetylcholinesterase inhibitors (Abstract and claim 10), as well as that the film-shaped medicament has a bilayer or multilayer structure wherein at least one of the layers contains the active substance. However, the Examiner acknowledges that '117 does not further teach any specific examples of acetylcholinesterase inhibitors which may be incorporated into the film-shaped dosage form.

The Examiner refers to '511 for teaching the use of the compound desoxypeganine (1,2,3,9-tetrahydropyrrolo[2,1-b] quinazoline; deoxypeganine) which is a noted inhibitor of acetylcholinesterase in orally, transdermally or sublingually administered pharmaceutical preparations. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to prepare a buccally-administrable, film-shaped dosage form comprising an acetylcholinesterase inhibitor such as deoxypeganine and/or its hydrochloride salt, and at least one other non-deoxypeganine-based active compound such as galanthamine.

Claims 4, 6-13, 15 and 27-37 remain rejected as being unpatentable over the combination of Asmussen, et al. '117 and Asmussen, et al. '511. The Examiner argues that '117 teaches the limitations of these claims, with the exception of teaching that the acetylcholinesterase inhibitor active compounds contribute to these percentages, or if they do, it is not expressly taught how much is attributed to said inhibitors. The Examiner refers to '511 for expressly teaching the multilayered dosage form as comprising a preferred percent weight range of 5-20% by weight of the desoxypeganine-based active substance. The Examiner further states that since only one reservoir layer is described in the delivery device, the layer containing the desoxypeganine-based drug – it then follows that the overall device contains the claimed amount of active compounds as well.

The Examiner also states that '117 fails to teach the percent weight ranges of desoxypeganine-based active substance either within the reservoir layer or the overall medicament. However, the Examiner concludes that since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that

each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to prepare a film-shaped dosage form comprising a deoxypeganine-based active substance at least one other active substance such as galanthamine and format the structure of the dosage form to produce the instantly claimed invention. The Examiner also concludes that in view of the combination of teachings, it would have been obvious to one of ordinary skill in the art to prepare a film-shaped dosage form comprising a deoxypeganine-based active compound and at least one other active compound such as galanthanmine and to format the structure of the dosage form as expressly taught by '117 to produce the presently claimed invention.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention for the reasons set forth in the prior Office action response. Additionally, even if one skilled in the art were to consider the combined teachings of the prior art, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully submit that the presently claimed invention differs from the teachings of Asmussen, et al. '117. Asmussen, et al. '117 teach buccal formulations of galanthanmine (Abstract). The formulations therein may contain a further cholinergic active agent acting on the central nervous system, preferably an inhibitor of acetylcholinesterase (Abstract; claim 10). Therefore, galanthanmine or one of its pharmaceutically acceptable salts or derivatives is an essential compounds of the buccal formulations of Asmussen, et al. '117.

It is also noted that although Asmussen, et al. '117 may indicate to combine galanthanmine with another inhibitor of acetylcholinesterase, the reference does not indicate to replace galanthanmine with another cholinergic active agent acing on the central nervous system. For this reason, Asmussen, et al. '117 do not make an orally administrable film-shaped medicament which would be obvious to one skilled in the art, wherein said medicament contains only another cholinergic active agent, such as, for example, deoxypeganine.

The Applicants also respectfully submit that the presently claimed invention differs from the teachings of Asmussen, et al. '511. Moreover, Asmussen, et al. '511 fail to make up for any of the deficiencies of the Asmussen, et al. '117. Asmussen, et al. '511 teach transdermal therapeutic systems of percutaneous administration of deoxypeganine, as well as a method for treating drug addition by administering deoxypeganine in a controlled and continuous manner to a patient in need thereof (claim 1). Asmussen, et al. '511 specify that the administration shall be orally or parenterally. However, the specification of Asmussen, et al. '511 only describes transdermal therapeutic systems in

detail (emphasis added). No technical information is provided with respect to the administration forms for oral or otherwise parenteral administration of deoxypeganine. Therefore, it is submitted that Asmussen, et al. '511 fail to provide sufficient information to one skilled in the art when combined with Asmussen, et al. '117 for teaching the presently claimed invention.

In view of the above, the Applicants submit that the orally administrable film-shaped medicament of present claim 1, which does not contain any other cholinergic active agent other than deoxypeganine or one of its pharmaceutically acceptable salts or derivatives, was not obvious to one skilled in the art at the time the present invention was made, that the present invention defined in the present claims is patentably distinguishable over the prior art of record and that each and every element of the present invention recited in the present claims is not set forth in the prior art. Moreover, one skilled in the art would not be motivated to combine the teachings of the prior art references of record to arrive at the presently claimed invention and even if such combination were done, each and every limitation of the presently claimed invention would not be taught.

Therefore, the Applicants strongly request that the obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art

references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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